

Response

Drawings

Figure 1 of the drawings has been corrected to clearly show reference numerals 20 and 80 pointing to different parts. The lead line of reference numeral 80 has been changed to clearly point to a hub of an IV catheter (20), while the lead line of reference numeral 20 points to an IV catheter.

In light of the changes to the drawings it is respectfully submitted that the Examiner's objections to the drawings are overcome.

Specification

Amendments to the specification accompanies this response. The amendments provide a proper antecedent basis for: a retraction mechanism, which is recited, for example, in claim 1; and an insert molded needle, which is recited, for example, in claim 15. The amendments are supported by the written description, drawings and claims as filed.

In light of the amendments to the specification, it is respectfully submitted that the Examiner's objections to the specification are overcome.

Claim Rejections – 35 U.S.C. § 112

Claims 1-24 and 38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claim 1

Applicants refer the Examiner to Figure 4 of the drawings which shows in detail the location of annular boss (106) of plunger tube (40) in relation to tubular body (32) of the needle holder assembly, and the location of annular recess (108) of tubular body (32) of the needle holder assembly in relation to plunger tube (40). As shown, annular boss (106) is shown as proximal to tubular body (32) of the needle holder assembly and annular recess (108) is shown as proximal to plunger tube (40).

Therefore, in contrast to the Examiner's position, annular recess (108) is proximal to plunger tube (40). Applicants do not understand annular recess (108) to be at least

distal to plunger tube (40). Thus, Applicants respectfully request that the Examiner's rejection be reconsidered and withdrawn.

Claim 1

Claim 1 has been amended to clarify that annular recess and annular boss are biased into releasable engagement with each other. The amendment is supported by the written description, drawings and claims as filed. In light of this amendment, Applicants believe the Examiner's rejection should be reconsidered and withdrawn.

Claims 15 and 38

Based on the amended description in the specification of the pending application at paragraph 10, lines 4-9, one skilled in the art would know what is meant by an insert molded needle. He or she would know that in subjecting a needle to an injection molding process, plastic is injected into a cavity and around the needle placed into the same cavity just prior to molding. The result is a single piece with the needle encapsulated by the plastic, i.e., an insert molded needle.

Further, the fundamental principle of 35 U.S.C. § 112, second paragraph, is that applicants can be their own lexicographers. Applicants can define in the claims what they regard as their invention essentially in whatever terms they choose as long as the terms are not used in ways that are contrary to accepted meanings in the art. A claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971).

Accordingly, Applicants request that the rejection of claims 1-24 and 38 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Claim Rejections – 35 U.S.C. § 102

Claims 1-5, 14-16, 23-24, 59 and 60 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,817,058 to Shaw ("Shaw"). To anticipate a claimed invention, a prior art reference must teach every aspect of the claimed invention. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986).

Claims 1-5, 14-16, 23-24

In light of the amendments to independent Claim 1, it is respectfully submitted that Shaw does not teach every aspect of Applicants' invention as defined by amended Claim 1, and, therefore, does not anticipate Applicants' amended Claim 1. As amended, Claim 1 recites that the annular recess and annular boss are biased into releasable engagement with each other. However, Shaw does not disclose an outwardly facing annular recess on a tubular body and an outwardly extending annular boss on a plunger tube biased into releasable engagement with each other.

Accordingly, Shaw does not anticipate Applicants' claimed invention as defined by amended Claim 1. Claims 2-5, 14-16 and 23-24 are also not anticipated by Shaw because these claims depend from Claim 1. As amended Claim 1 is not anticipated by Shaw, neither are the claims depending from it. Applicants request that the rejection of Claims 1-5, 14-16 and 23-24 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Claim 59

In light of the amendment to independent Claim 59, it is respectfully submitted that Shaw does not teach every aspect of Applicants' invention as defined by amended Claim 59, and, therefore, does not anticipate Applicants' amended Claim 59. As amended, Claim 59 recites that an outwardly facing annular recess is releasably engaged with an outwardly extending annular boss in combination with needle support section extending through the retraction mechanism and protruding forwardly beyond the tubular housing. However, Shaw does not disclose this combination.

Accordingly, Shaw does not anticipate Applicants' claimed invention as defined by amended claim 59. Applicants request that the rejection of Claim 59 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Newly added Claim 67 depends from Claim 59. Both Claim 67 and the amendments to Claim 59 are supported by the written description, drawings and claims as filed.

Claim 60

As to independent Claim 60, Figure 6 of Shaw does not disclose a flash chamber with an interior space that is viewable through no more than two layers of clear plastic.

In particular, Figure 6 of Shaw shows that the interior of flash chamber 32 is viewed through at least three layers: the wall of flash chamber 32, the wall 19 of plunger tube 18 and the wall of housing 16. Therefore, Shaw does not anticipate Claim 60 and Applicants request that the rejection of Claim 60 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Claims 25-26, 33-37, 41, 44 and 45 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,096,005 to Botich ("Botich"). Again, to anticipate a claimed invention, a prior art reference must teach every aspect of the claimed invention. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). It is respectfully submitted that Botich does not teach every aspect of Applicants' invention as defined by independent Claim 25, and, therefore, does not anticipate Claim 25.

Botich fails to disclose a plunger assembly having a plunger tube releasably engaged with the tubular body inside the housing, as recited in Claim 25. The Examiner identifies the needle of Botich, or reference numeral 625, as the tubular body. In relation to Figures 11-13 of Botich, the plunger 624 in Botich is not releasably engaged with the needle 625 or any part of needle head 630. Botich discloses that the forward end 740 of the plunger 624 is shaped to mate with cooperating wedge shaped surfaces 739 of the hooks 639 to facilitate the spreading of the fingers 637 to release the needle head 630. Col. 12, lines 2-6. The plunger 624 engages the hooks when the plunger 624 is urged forward within the barrel 622 which causes the fingers 637 to spread radially outward by flexing or breaking, thus releasing the head 630 of the needle 625. Col. 12, lines 6-12.

Applicants also contend that identifying the needle as the tubular body is incorrect. Claim 25 recites "a needle holder assembly having a tubular body" The Examiner identifies needle retainer 656 as the needle holder assembly. Botich fails to disclose the needle retainer 656 having a needle 625. Instead, the needle retainer of Botich retains the needle. FIGS. 11-12.

Accordingly, Botich does not anticipate Applicants' claimed invention as defined by Claim 25. Claims 26, 33-37, 41, 44 and 45 are also not anticipated by Botich

because these claims depend from Claim 25. As Claim 25 is not anticipated by Botich, neither are the claims depending from it. Applicants request that the rejection of Claims 25-26, 33-37, 41, 44 and 45 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claim 17

Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,817,058 to Shaw ("Shaw"). Applicants traverse this rejection and respectfully contend that the Examiner has failed to establish a *prima facie* case of obviousness. First, Claim 17, which depends from amended Claim 1, requires that annular recess and annular boss are biased into releasable engagement with each other. This recited element is absent from Shaw. Second, as admitted by the Examiner, Shaw fails to disclose a needle sonically welded into the needle holder assembly. Third, as only Shaw has been cited, there is a lack of a reference that discloses the missing elements. Thus, the obviousness rejection is legally insupportable and should be withdrawn.

Claim 18

Claim 18 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Shaw in view of U.S. Patent No. 5,989,220 to Shaw et al. ("Shaw et al."). Applicants traverse this rejection and respectfully contend that the Examiner has failed to establish a *prima facie* case of obviousness. First, Claim 18, which depends from Claim 14, which depends from Claim 4, which depends from amended Claim 1, requires that annular recess and annular boss are biased into releasable engagement with each other. This recited element is absent from Shaw. Second, there is a lack of a reference that discloses this missing element. Third, no objective reason has been given to combine the teachings of Shaw and Shaw et al. Thus, the obviousness rejection is legally insupportable and should be withdrawn.

Claim 27

Claim 27 is rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,096,005 to Botich ("Botich"). Applicants traverse this rejection and

respectfully contend that the Examiner has failed to establish a *prima facie* case of obviousness. First, Claim 27 has all the limitations of Claims 25 and 26. As discussed above in relation to rejections under 35 U.S.C. § 102(b), Botich does not teach every aspect of Applicants' invention as defined by Claims 25 and 26, and therefore does not teach every aspect of Claim 27. Second, as admitted by the Examiner, Botich fails to disclose a plastic end cap that is colored. Third, as only Botich has been cited, there is a lack of a reference that discloses the missing elements. Hence, the obviousness rejection is legally insupportable and should be withdrawn.

Allowable Subject Matter

The allowance of Claims 46-58 and 61-66 is acknowledged with appreciation.

Submitted herewith is a check in the amount of \$9 to accommodate the additional claim added by this Amendment. The Commissioner is hereby authorized to charge any additional fee that may be required or credit any overpayment to the Locke Liddell & Sapp LLP Deposit Account No. 12-1781.

Respectfully submitted,

By:



Kristen R. Paris
Registration No. 52,092

Date: April 13, 2004
LOCKE LIDDELL & SAPP LLP
2200 Ross Avenue, Suite 2200
Dallas, TX 75201-6776
(214) 740-8678 (telephone)
(214) 740-8800 (facsimile)